

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER
ASSOCIATION *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

Case No. 1:23-cv-00707

DEFENDANTS' MOTION TO VACATE SCHEDULING ORDER

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INTRODUCTION

Venue is improper in this district for the reasons set forth in Defendants’ Motion to Dismiss. *See* ECF No. 39 (Defs.’ Mot.). That motion presents significant threshold issues that should be resolved before this case proceeds. Namely, because the Court lacks subject-matter jurisdiction over the claims brought by Plaintiff the National Infusion Center Association (NICA), and because NICA’s residency is this lawsuit’s only connection to this district, venue here is improper, and this case should be dismissed. As a result, the Court should vacate the current scheduling order and adjudicate Defendants’ Motion to Dismiss before further merits briefing continues. If the Court grants Defendants’ motion, no further briefing will be required; if the Court denies it, then the Court can order the parties to submit a joint scheduling proposal as to further merits briefing. Deferring summary-judgment briefing until after Defendants’ Motion to Dismiss is resolved is warranted because it will likely conserve the Court’s and the parties’ resources and because a modest delay in the current briefing schedule is unlikely to prejudice Plaintiffs. Accordingly, Defendants respectfully request that the Court vacate the current scheduling order, *see* Order, ECF No. 34, and adjudicate Defendants’ Motion to Dismiss before further summary-judgment briefing is ordered.

BACKGROUND

There are three Plaintiffs in this litigation. Only one of the three—the National Infusion Center Association (NICA), a Texas corporation—“resides in this district.” Compl. ¶¶ 19–20, ECF No. 1. The other two—the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Global Colon Cancer Association (GCCA)—reside elsewhere. *Id.* ¶¶ 19, 22–23. NICA’s residency is the only basis for venue that is alleged in the complaint. *Id.* ¶ 19. Accordingly, because the Court lacks subject-matter jurisdiction over NICA’s claims, venue is not proper in this district. *See* Defs.’ Mot. at 16–17.

Plaintiffs filed this suit on June 21, 2023, almost a year after the Inflation Reduction Act (IRA) became law on August 16, 2022. *See* Compl.; Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001–11003 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). Plaintiffs ask the Court to nullify key provisions of the IRA, in which Congress authorized the Secretary of Health and

Human Services to try and negotiate a better deal for Medicare beneficiaries and the American taxpayer on some of the pharmaceutical industry's most lucrative drugs. Plaintiffs seek that relief before any prices are agreed upon (by August 2024 for the first 10 selected Part D drugs) and before any new prices take effect (no earlier than 2026 for those first 10 drugs).

Defendants filed a timely motion to dismiss on August 28, 2023. Defendants asserted that this action should be dismissed for improper venue because NICA lacks standing, and because it failed to channel its claims through the administrative process before suing in federal court as required under the Medicare statute. *See* Defs.' Mot. Defendants argued that NICA—which allegedly represents outpatient facilities that, among other services, administer infusion drugs covered under Medicare Part B—lacks associational standing because it has not identified any member, let alone one that would have Article III standing on its own. *See id.* at 8–12. Defendants explained that NICA would need to allege that an identified member administers a particular drug covered under Part B that is going to be selected for negotiation—allegations that are unsurprisingly absent from the complaint given that, in at least the first two negotiation cycles, no infusion drugs under Part B will be selected for purposes of coverage under Part B. *See id.* at 9–10.

On August 28 and August 29, 2023, Defendants conferred with Plaintiffs about the present motion; Plaintiffs stated that they oppose the motion.

Summary-judgment briefing is currently scheduled to conclude on November 17, 2023. *See* ECF No. 34. Plaintiffs filed their summary-judgment motion on August 10, 2023. *See* Pls.' Mot. for Summ. J., ECF No. 35. Defendants' combined cross-motion and opposition is currently due on September 29, 2023; Plaintiffs' opposition and reply is due on October 26, 2023; and Defendants' reply is due on November 17, 2023. *See* ECF No. 34.

ARGUMENT

Defendants' Motion to Dismiss, which presents the threshold question of whether venue is proper in this Court, should be decided before further summary-judgment briefing. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 432–33 (2007) (order dismissing case on venue grounds

is “a threshold, nonmerits” “determination that the merits should be adjudicated elsewhere”); 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1349 (3d ed.) (Rule 12(b) motions “present preliminary or threshold matters that normally should be adjudicated early in the action”). The Fifth Circuit has emphasized that “disposition of [a venue-related motion] should . . . take[] a top priority in the handling of [a] case.” *In re Horseshoe Ent.*, 337 F.3d 429, 433 (5th Cir. 2003); *see also In re Apple Inc.*, 979 F.3d 1332, 1337 (Fed. Cir. 2020) (“Although district courts have discretion as to how to handle their dockets, once a party files a [venue-related] motion, disposing of that motion should unquestionably take top priority.”); *E. Tex. Boot Co., LLC v. Nike, Inc.*, No. 2:16-CV-0290-JRG-RSP, 2017 WL 2859065, at *2 (E.D. Tex. Feb. 15, 2017) (similar). Accordingly, “[u]nder Fifth Circuit law, a trial court must prioritize [venue-related motions] over substantive proceedings.” *In re Apple Inc.*, No. 2023-120, 2023 WL 2359699, at *1 (Fed. Cir. Mar. 6, 2023). For the same reasons, courts in this Circuit strongly discourage parties from briefing substantive motions prior to venue-related ones. *See, e.g., Order, U.S. Navy Seals 1-26 v. Biden*, No. 4:21-cv-01236 (N.D. Tex. May 7, 2022), ECF No. 150 (rejecting venue arguments because defendants raised issue after litigating preliminary injunction motion); *see also In re Planned Parenthood Fed’n of Am., Inc.*, 52 F.4th 625, 631 (5th Cir. 2022) (faulting defendants’ delay in pressing venue argument, where the motion was not filed until “months into the discovery period” (citation omitted)).

Pursuant to the Fifth Circuit’s direction and in the interest of efficiency, this Court should prioritize resolution of Defendants’ timely filed motion to dismiss for improper venue and pause further merits briefing in the interim. Engaging in summary-judgment briefing while the Court weighs Defendants’ Motion to Dismiss would be inefficient; if that motion is granted, “this Court will have needlessly expended its energies familiarizing itself with the intricacies of a case that” will be dismissed altogether or that will “be heard by another judge.” *Rivers v. Walt Disney Co.*, 980 F. Supp. 1358, 1360–61 (C.D. Cal. 1997); *see also* 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1349 (3d ed.) (early adjudication of “Rule 12(b) [motions] [is] likely to produce an overall savings in time and resources as well as avoid delay in the disposition of cases, thereby benefiting both the parties and the courts”). Those inefficiencies will compound if this case is ultimately refiled outside of the

Fifth Circuit—a real possibility, given the residence of the other two Plaintiffs. *See* 28 U.S.C. § 1391(c)(2) (if “a plaintiff, [a corporation resides] only in the judicial district in which it maintains its principal place of business”); Compl. ¶¶ 22–23 (PhRMA and GCCA are headquartered in Washington, D.C.). In that instance, if the remaining Plaintiffs refile this case, Defendants may raise other threshold defenses, and then, if the case proceeded to the merits, the parties would need to prepare new summary-judgment briefs based on different circuit law.¹

If Defendants’ Motion to Dismiss is granted, then no summary-judgment briefing will be necessary at all. And even if the motion is denied (or if this case is refiled elsewhere), a slight delay in merits briefing would not prejudice Plaintiffs. Even assuming the remaining Plaintiffs identify members that will suffer harm resulting from a particular drug being selected for negotiation and provided at a negotiated price, the earliest that any new prices will take effect is 2026. And, as explained in greater detail in Defendants’ Motion to Dismiss, the hypothesized harm to NICA’s members would occur even further in the future—2028 or later. *See* Defs.’ Mot. at 9–11. Summary-judgment briefing is currently scheduled to conclude on November 17, 2023, *see* ECF No. 34—more than two years before any negotiated drug prices will take effect.

Plaintiffs’ own litigation choices also indicate that they are unlikely to be prejudiced by a temporary deferral of the summary-judgment briefing deadlines. The IRA became law on August 16, 2022; Plaintiffs waited more than ten months, until June 21, 2023, to file this facial challenge to the statute. In the ensuing months, they have not alleged that they face any immediate harm absent a favorable ruling by this Court. Accordingly, there is no indication that Plaintiffs will be prejudiced by the requested delay of the summary-judgment briefing schedule.

¹ Similar inefficiencies would result even if this Court transferred—rather than dismissed—this action on venue grounds. *See Murphy v. FDIC*, 208 F.3d 959, 964 (11th Cir. 2000) (agreeing with four other circuits that, in federal question cases transferred pursuant to § 1404(a), “the transferee court should apply its own interpretation of federal law”); *see also In re Whole Foods Mkt., Inc.*, 163 F. Supp. 3d 385, 388 (W.D. Tex. 2016) (“transferee court” in multidistrict litigation “must apply the law of its own circuit when analyzing questions of federal law”). For the reasons stated in Defendants’ Motion to Dismiss, however, dismissal, not transfer, is warranted here. *See* Defs.’ Mot. at 17–18.

Further, requiring continued merits briefing that may prove to be unnecessary upon adjudication of Defendants’ Motion to Dismiss would cause a needless waste of resources, among other reasons because the government is actively defending more than a half-dozen similar challenges to the IRA on a similar timeline. In these circumstances, a short delay in proceedings while the Court considers Defendants’ threshold arguments on jurisdiction and venue is warranted. *See Mulvey v. Vertafore, Inc.*, No. 3:21-CV-00213-E, 2021 WL 4137522, at *1 (N.D. Tex. May 7, 2021) (temporarily staying the case when the plaintiff did “not articulate any specific harm he will suffer by a short delay, at the outset of this case, in order to resolve” venue-related motion), *subsequent determination*, No. 3:21-cv-213-E-BN, 2021 WL 3089386 (N.D. Tex. Jul. 22, 2021) (granting transfer-of-venue motion); *see also* Order, *Texas v. Garland*, No. 5:23-CV-034-H (N.D. Tex. Mar. 6, 2023), ECF No. 30 (order granting in part motion to stay pending resolution of improper-venue motion after defendants asserted that plaintiff failed to allege prejudice from any temporary delay).

To be sure, Defendants previously joined a request for the scheduling order that Defendants now seek to vacate. *See* ECF No. 33 (agreeing “that this case presents legal questions that can properly be resolved through dispositive motions, without the need for discovery,” and that the parties “intend[ed] to file cross-motions for summary judgment”). But Defendants did not become aware of the full scope of the venue problem until recently, after Plaintiffs filed their summary-judgment papers—which only reinforced the tenuous nature of Plaintiffs’ theory of venue. This development is good cause for the Court to revisit the briefing schedule. Under these circumstances, the parties’ prior agreement on summary-judgment briefing is not a basis to defer a ruling on Defendants’ timely threshold motion.² *See In re Horseshoe Ent.*, 337 F.3d at 433 (where defendant “filed its motion to transfer timely and before it filed its answer,” “disposition of that motion should have taken a top priority in the handling of this case”). Further, should the Court deny Defendants’ Motion to Dismiss, the Court could then invite the parties to submit a new proposed scheduling order, which would

² Defendants timely filed their Motion to Dismiss by the deadline to answer or otherwise respond to the complaint. The Court previously ordered that Defendants need not file an answer in this action. *See* ECF No. 34. Had an answer been due, it would have been due on August 28, 2023—the date Defendants filed their motion.

closely resemble the prior scheduling order, both in terms of the relative time between briefs and the page limits for each brief. For now, however, the Court should adjudicate Defendants' Motion to Dismiss, which, if granted, will eliminate the need for any further summary-judgment briefing.

CONCLUSION

For these reasons, the Court should vacate the previous scheduling order, ECF No. 34, and adjudicate Defendants' Motion to Dismiss before further summary-judgment briefing is ordered.

Date: August 29, 2023

Respectfully submitted,

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